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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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FAY KAPLUN & MARCIN, LLP
150 BROADWAY, SUITE 702
NEW YORK, NY 10038

EXAMINER	
FLORY, CHRISTOPHER A	
ART UNIT	PAPER NUMBER
3762	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,199	KRONZON, ITZHAK	
	Examiner	Art Unit	
	CHRISTOPHER A. FLORY	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,8,10-15 and 17-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,8,10-15 and 17-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 17 July 2009 with respect to the rejection of claims 1-5, 7, 8, 10-15 and 17-26 under §103 as obvious over Friedman'167 in view of Venrooij'867 have been fully considered but they are not persuasive.

Regarding claims 1, 14 and 20t is noted that Applicant again argues that the contacts 25 as shown in Friedman cannot be used as electrodes because Friedman'167 does not specifically state them to be electrodes (See page 3, paragraph 2 and page 7, paragraph 1), and that even if they are they are not covered by a sheath. Examiner maintains that the contacts are capable of functioning as electrical contacts to generate electrical stimulation, the instant claims being directed to an apparatus, such that the intended use of the instant claims need not be explicitly recited in the rejecting reference wherein the recited structure is capable of performing that function. If the electrode rings were removed, the electrical current would still pass through the contacts 25 to the surface of the probe, where the current would be transmitted to tissue as the path of least resistance. It is also noted that the side portions of the contacts 25 can be considered as covered by the sheet 30 to sufficiently satisfy the language of being "covered by a portion of the sheath.

In response to Applicant's arguments regarding adhesive strips (see page 3), it is noted that the disclosure of additional structure in a prior art reference is irrelevant wherein the prior art reference already discloses each and every limitation of the instant claims.

Applicant argues that Venrooij'867 fails to disclose an insulating sheath with electrodes embedded therein such that the electrodes are covered by the insulating member. However, it is noted that Friedman'167 has already been established to teach embedded electrodes as previously stated. Additionally, Venrooij'867 clearly shows that the insulating sheath covers the electrodes in the figures and provides motivation for covering the electrodes as explained below. Thus, the combination of Friedman'167 and Venrooij'867 would arrive at embedded electrodes covered by the sheath as recited in the instant claims.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-5, 7, 8, 10, 12-15 and 17-27 stand rejected under 35 U.S.C. 103(a) as obvious over Friedman (US Patent Publication 2003/0097167, hereinafter referred to as Friedman'167) in view of Van Venrooij et al. (US 7,212,867, hereinafter Venrooij'867).

Regarding claims 1-5, 10, 14 and 19, Friedman'167 discloses a medical apparatus used to treat cardiac arrhythmia comprising a flexible probe for accessing a patient's esophagus via the mouth with a proximal end which remains outside the patient and a distal end within the esophagus (TITLE; ABSTRACT; paragraphs [7], [10] and [32]); an echocardiography transducer coupled to the distal end at a predetermined

location within the esophagus relative to the heart to perform transesophageal echocardiography (Fig. 1 TEE probe 3; paragraphs [6], [10] and [32]); and a plurality of electrodes spaced along a longitudinal axis of the probe embedded in the sheath (Fig. 2, electrodes 26; Fig. 3, leads 1-8) each coupled to a wire lead extending along the probe to a power source (paragraphs [9], [28] and [29]) for delivering a cardioversion or defibrillation current via the esophagus (paragraphs [15]-[17] and [36]-[38]).

Regarding claims 24 and 25, and further regarding claims 1, 14 and 20, Friedman'167 clearly shows in Figure 5 that the electrode assembly is C-shaped and non-annular. Alternatively, it is noted that the electrical contacts embedded within the sheath are functional as electrodes in an operative position themselves, and clearly define a non-annular shape with a length no more than half of the circumference of the probe which is embedded in the sheath, which also means an opening of at least 110 degrees. Still further in the alternative, Venrooij'867 describes non-annular C-shaped electrodes for directional stimulation and recording to improve localization of signals (title; abstract; column 15, line 39; Figures 3, 4, 6, 18). Shadduck'419 teaches non-annular electrodes (Figs. 5A-F) to be applied to the lower esophageal sphincter to induce injury healing response (abstract; column 9, lines 6-56). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Friedman'167 with the non-annular electrodes as taught by any one of these references to provide Friedman'167 with the respective advantages described in this paragraph as taught by Venrooij'867, Shadduck'419, Atlee'116 and Melnikoff'549.

Further regarding claims 24 and 25, given the interpretation of Friedman'167 that the electrical contacts within the sheath are functional electrodes, Friedman'167 clearly shows electrodes with a length no more than half of the circumference of the probe and an opening of at least 110 degrees. Alternatively, regarding the non-annular electrode ring shown in Fig. 5, although it is not expressly disclosed that the length be no more than half the circumference, it would have been obvious to one having ordinary skill in the art at the time of the invention to construct the electrode with such a length or angle of opening since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (*In re Aller*, 105 USPQ 233) or optimum value of a result effective variable (*In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)) involves only routine skill in the art. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the electrode as taught by Friedman'167, because it provides a means of providing electrical stimulation to the esophagus as well as a means of snapping/clamping the electrode to the probe body and since it appears to be an arbitrary design consideration which fails to patentably distinguish the instant application over Friedman'167.

Still further in the alternative, Venrooij'867clearly shows a non-annular electrode with a circumferential length no more than half that of the circumference of the probe, and with an opening of at least 110 degrees. It would have been an obvious matter of design choice to one of ordinary skill in the art at the time of the invention to modify the system as taught by Friedman'167 with the electrodes as shown in these references,

because Applicant has not disclosed that a length of less than half the circumference or an opening angle of at least 110 degrees provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the electrodes as disclosed in Friedman'167, because it provides a means of providing electrical stimulation to the esophagus as well as a means of snapping/clamping the electrode to the probe body and since it appears to be an arbitrary design consideration which fails to patentably distinguish the instant application. Therefore, it would have been an obvious matter of design choice to modify the system of Friedman'167 to obtain the invention as specified in the claim(s).

Regarding claims 7, 17, 18, 26 and 27, and further regarding claims 1 and 14, Friedman'167 discloses the electrodes mounted on or within, i.e. embedded in, a flexible sheath which is sized to be received over a distal portion of the probe and fixed thereon at a predetermined location relative to the echocardiography transducer (paragraphs [6], [7], [10]-[12] and [32]), the sheath being made of a biocompatible material (paragraph [32] discloses a sheath made of silicone) wherein the sheath/electrode is selectively mountable on and removable from the scope portion (paragraphs [11], [12] and [32]). It is noted that the electrical contacts within the sheath are functional as electrodes in an operative position themselves, and also that the act of clamping the electrode rings to the sheath can be reasonably interpreted to mean a sheath including an electrode.

Further regarding claims 1, 14 and 20, Friedman'167 discloses the invention substantially as claimed including embedded electrodes, but does not expressly disclose that the electrodes are embedded in such a way that the electrodes are covered by a portion of the sheath. In the same field of endeavor, Venrooij'867 teaches the use of an insulative sheath that covers portions of the electrodes to directionalize and limit the tissue to which electrical stimulation current is delivered (column 6, lines 48-61). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the embedded electrodes of Friedman'167 to be covered by a portion of the sheath as taught by Venrooij'867 to provide Friedman'167 with the same advantage of directionalizing the stimulation current to the desired tissue.

Regarding claim 8, Friedman'167 discloses that the sheath can also be permanently bonded to the probe (paragraphs [34] and [35]).

Regarding claims 12 and 13, Friedman'167 discloses the electrode having a length of 7-10mm along an axial direction of the probe and being separated from a second electrode by a distance of 5-8mm (Fig. 3).

Regarding claim 15, Friedman'167 discloses an electrode assembly that is one of a single use assembly and a multiple use assembly, in that a single use assembly is defined identically to a removable and selectively mountable assembly, and a multiple use assembly is synonymous with a permanently bonded assembly as discussed with regards to claim 6, 8 and 9.

Regarding claim 20, Friedman'167 discloses a method of treating a heart of a patient comprising the steps of inserting a flexible echocardiography probe into the

patient's esophagus, performing an echocardiography to analyze the condition of the heart, and applying electric current to the at least one cardioversion electrode to supply a current to the heart (paragraphs [13]-[17]).

Regarding claim 21, Friedman'167 discloses performing an additional echocardiography immediately after the cardioversion using the echocardiography transducer (paragraph [18]).

Regarding claims 22 and 23, Friedman'167discloses coupling the electrode sheath to the probe prior to inserting the device into the esophagus and disposing of the sheath after completing the procedure (paragraphs [6], [7], [10], [11], [12], [32] and [33]).

4. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman'167 in view of Venrooij'867, or in the alternative is unpatentable over Friedman'167 in view of Venrooij'867 and further in view of Shadduck'419.

Regarding claim 11, Friedman'167 discloses the invention substantially as claimed but does not expressly disclose that the electrode is formed of a titanium foil. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system and method as taught by Friedman'167 with a titanium foil electrode, since it is well known in the art that titanium is a good material for electrode construction due to its relatively low cost, durability, biocompatibility, and good electrical conduction properties. Alternatively, Shadduck'419 teaches electrodes made of titanium, as titanium is a suitable conductive material which is adapted to deliver RF energy to soft tissue of the esophageal lumen without ablating and necrosing surface tissue to a significant degree (column 9, lines 57-63). Therefore, it would have been

obvious to one of ordinary skill in the art at the time of the invention to modify Friedman'167 with the titanium electrodes as taught by Shadduck'419 to provide Friedman'167 with the same advantage of stimulating the esophageal lumen without ablating and necrosing the tissue.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Christopher A. Flory/

25 September 2009

/George Manuel/
Primary Examiner